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UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA : Hon. Esther Salas

v. : Criminal No. 21-907-ES

DAVID WOROBOFF, : 18 U.S.C. § 2 GEORGE WILLARD, : 18 U.S.C. § 371

RANDALL MILLS, and : 18 U.S.C. § 1349

LE THU

INDICTMENT

The Grand Jury for the District of New Jersey charges:

COUNT ONE (Conspiracy to Commit Health Care Fraud)

1. Unless otherwise indicated, at all times relevant to this Indictment:

Relevant Individuals and Entities

- a. Defendant David Woroboff ("defendant WOROBOFF") was a resident of California. Defendant WOROBOFF was the Chief Executive Officer of a telemedicine company incorporated under the laws of Nevada (the "Telemedicine Company").
- b. Defendant George Willard ("defendant WILLARD") was a resident of Michigan and the Chief Operating Officer of the Telemedicine Company.
- c. Defendant Randall Mills ("defendant MILLS") was a resident of Texas and an employee of the Telemedicine Company.

- d. Defendant Le Thu ("defendant THU") was a medical doctor and a resident of Massachusetts. From in or around 2014 through in or around 2019, defendant THU worked as a health care provider ("HCP") for the Telemedicine Company.
- e. Physician-1, a co-conspirator not charged in this Indictment, was a physician licensed to practice in New Jersey who worked as an HCP for the Telemedicine Company.

Compounding

- f. In general, "compounding" was a practice in which a licensed pharmacist, or a licensed physician, combined, mixed, or altered ingredients of a drug to create a medication tailored to the needs of an individual patient. Pharmacies engaged in the practice of compounding were referred to as "compounding pharmacies."
- g. Compounded drugs were not approved by the Food and Drug Administration ("FDA"); that is, the FDA did not verify the safety, potency, effectiveness, or manufacturing quality of compounded drugs. Generally, compounded drugs were prescribed by a physician when an FDA-approved drug did not meet the health needs of a particular patient. For example, if a patient was allergic to a specific ingredient in an FDA-approved medication, such as a dye or preservative, a compounded drug could be prepared excluding the substance that triggered the allergic reaction. Compounded drugs also could be prescribed when a patient could not consume a medication by traditional means,

such as an elderly patient or child who could not swallow an FDA-approved pill and needed the drug in a liquid form that was not otherwise available.

The Medicare Program

- h. Medicare was a federally-funded program established to provide medical insurance benefits for individuals age 65 and older and certain disabled individuals who qualified under the Social Security Act. Individuals who received benefits under Medicare are referred to as "Medicare beneficiaries."
- i. Medicare was administered by the Center for Medicare and Medicaid Services ("CMS"), a federal agency under the United States Department of Health and Human Services.
- j. Medicare was divided into four parts, which helped cover specific services: Part A (hospital insurance), Part B (medical insurance), Part C (Medicare Advantage), and Part D (prescription drug coverage).
- k. Medicare Part B covered non-institutional care that included physician services and supplies, such as durable medical equipment ("DME"), that were needed to diagnose or treat medical conditions and that met accepted standards of medical practice. Medicare Part D covered prescription drugs, including certain compounded medications.
- 1. Medicare was a "health care benefit program," as defined by 18 U.S.C. § 24(b), and a "Federal health care program," as defined by 42 U.S.C. § 1320a-7b(f), that affected commerce.
- m. Medicare would not reimburse claims for services that it knew were procured through kickbacks or bribes. Such claims were deemed false and

fraudulent because they violated Medicare laws, regulations, and program instructions, and violated federal criminal law. For example, where a DME order or a compound prescription was procured through the payment of a kickback in violation of the federal Anti-Kickback Statute ("AKS"), a claim to Medicare for reimbursement for that order was fraudulent. Medicare also would not reimburse claims unless those claims were for medically necessary services. By implementing these restrictions, Medicare aimed to preserve its resources, which were largely funded by United States taxpayers, for those elderly and other qualifying beneficiaries who had a genuine need for medical services.

TRICARE

- n. TRICARE was a health care program of the United States Department of Defense ("DoD") Military Health System that provided coverage for DoD beneficiaries worldwide, including active-duty service members, National Guard and Reserve members, retirees, their families, and survivors. The Defense Health Agency, an agency of the DoD, was the military entity responsible for overseeing and administering the TRICARE program.
- o. TRICARE was a "health care benefit program," as defined by 18 U.S.C. § 24(b), and a "Federal health care program," as defined by 42 U.S.C. § 1320a-7b(f), that affected commerce.
- p. TRICARE-authorized suppliers of health care services could only submit claims to TRICARE for medically necessary services. TRICARE would not reimburse claims for services that it knew were procured through kickbacks or bribes. Such claims were deemed false and fraudulent because they violated

TRICARE laws, regulations, and program instructions, and violated federal criminal law. For example, where a DME order or a compounded prescription was procured through the payment of a kickback in violation of the AKS, a claim to TRICARE for reimbursement for that order was fraudulent. By implementing these restrictions, TRICARE aimed to preserve its resources, which were largely funded by United States taxpayers, for those qualifying beneficiaries who had a genuine need for medical services.

The Conspiracy

2. From in or around May 2014 through in or around April 2017, in the District of New Jersey, and elsewhere, defendants

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did knowingly and intentionally conspire and agree with others to knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud a health care benefit program and to obtain, by means of false and fraudulent pretenses, representations, and promises, any of the money or property owned by, and under the custody and control of, a health care benefit program, as defined by 18 U.S.C. § 24(b), in connection with the delivery of or payment for health care benefits, items and services, contrary to Title 18, United States Code, Section 1347.

Goal of the Conspiracy

3. The goal of the conspiracy was for the defendants and their coconspirators to unlawfully enrich themselves and others by causing the submission of false and fraudulent claims to health care benefit programs.

Manner and Means of the Conspiracy

- 4. It was part of the conspiracy that:
- a. Prior to in or about May 2014, the Telemedicine Company's business model was for the company's registered nurses to first speak with beneficiaries and assess their conditions. Thereafter, physicians associated with the Telemedicine Company would speak with the beneficiaries to treat them and prescribe medications as the physicians deemed medically necessary and appropriate for each particular beneficiary. Prescriptions, if appropriate, would be sent to pharmacies as directed by the beneficiaries.
- b. In or around May 2014, defendant WOROBOFF, defendant WILLARD, defendant MILLS, and their co-conspirators began to operate a separate business model focused on compounded medications, and later, DME. This side of the Telemedicine Company's business was designed to generate a high volume of prescriptions for compounded medications and DME. As part of this scheme, defendant WOROBOFF, defendant WILLARD, defendant MILLS, defendant THU, and their co-conspirators arranged for the Telemedicine

Company to generate prescriptions for compounds and DME without regard to medical necessity and through the payment of kickbacks.

- c. In or around May 2014, defendant WOROBOFF, defendant WILLARD, defendant MILLS, and their co-conspirators began to communicate with individuals who identified beneficiaries located in New Jersey and elsewhere through the use of marketing call centers under their direction (the "Marketers"). The Marketers sought to partner with a telemedicine company to generate prescriptions for compounded medications and DME ("Compound Orders" and "DME Orders," respectively), and then send the Compound Orders and DME Orders to particular compounding pharmacies and DME supply companies.
- d. In or around May 2014, defendant WOROBOFF, defendant WILLARD, and defendant MILLS arranged for the Telemedicine Company to generate Compound Orders in exchange for payment from the Marketers. Subsequently, beginning in or around August 2015, defendant WOROBOFF and defendant WILLARD also arranged for the Telemedicine Company to generate DME Orders in exchange for payment from the Marketers.
- e. The Marketers provided beneficiaries' medical information directly to the Telemedicine Company. Thereafter, Telemedicine Company contractors based in the Philippines reviewed the beneficiary information. While the Telemedicine Company referred to these contractors as "nurses" when corresponding with HCPs, they were not U.S. registered nurses and generally did not communicate with the beneficiaries. After the contractors had reviewed the

beneficiary information, each beneficiary was assigned to an HCP associated with the Telemedicine Company for a "consult."

- f. Defendant WOROBOFF, defendant WILLARD, defendant MILLS, and their co-conspirators knew that the "nurses" located in the Philippines were not U.S. registered nurses. Defendant WOROBOFF, defendant WILLARD, defendant MILLS, and their co-conspirators also knew that HCPs did not speak with beneficiaries in conjunction with prescribing compounded medication and DME. In fact, defendant WOROBOFF and defendant MILLS falsely informed HCPs that "nurses" had already consulted with the beneficiaries, taken their medical histories, and determined that compounded medication or DME was medically appropriate for the beneficiaries.
- g. For example, on or about September 10, 2014, Physician-1 emailed defendant MILLS that he was interested in prescribing compounds and was licensed in New Jersey, among other states. Defendant MILLS responded by falsely informing Physician-1 that a "nurse triages the patient and provides you a details [sic] medical history and allergies on the patient. Most [] doctors have sufficient information to write the scripts without talking to the patient but talking to the patient is always an option." Physician-1 ultimately wrote prescriptions for the Telemedicine Company for beneficiaries located in New Jersey.
- h. To induce HCPs to write prescriptions without regard for medical necessity, defendant WOROBOFF, defendant WILLARD, and defendant MILLS agreed to pay certain HCPs kickbacks for each compounding prescription.

For example, defendant THU, defendant WOROBOFF, defendant WILLARD, and defendant MILLS agreed that the Telemedicine Company would pay defendant THU \$35 for each compounding prescription. Defendant THU thereafter generated Compound Orders without speaking to the beneficiaries and in exchange for these kickback payments.

- i. Despite the admonitions from representatives of the Telemedicine Company that the HCPs did not need to speak with beneficiaries, some HCPs still endeavored to do so. In order to assure that the HCPs generated Compound Orders and DME Orders for the Marketers—without regard for whether such orders were medically necessary—defendant WOROBOFF, defendant WILLARD, defendant MILLS, and their co-conspirators steered consults away from those HCPs who sought to speak with patients, and toward those they knew did not speak with patients. To formalize this process, the Telemedicine Company maintained an internal chart of HCPs for the contractors to utilize when assigning consults that had a column labeled "Speak to Px [Patient]." The chart indicated that only a few HCPs always spoke to patients, and contractors were encouraged to rely on those HCPs that did not speak to patients.
- j. Similarly, to ensure that the Telemedicine Company generated Compound Orders and DME Orders without regard to medical necessity, defendant WOROBOFF, defendant WILLARD, defendant MILLS, and their co-

conspirators agreed that the Telemedicine Company would not send consults to HCPs who had significant rates of denying prescriptions.

- k. To generate as many Compound Orders and DME Orders as possible and increase the payments that they received from the Marketers, defendant WOROBOFF, defendant WILLARD, and their co-conspirators agreed to send consults to HCPs who were not licensed in the states in which the beneficiaries were located, in violation of certain state telemedicine laws.
- 1. In some states, pharmacists were suspicious of prescriptions written by out-of-state HCPs or by HCPs located far from the pharmacy. To conceal the true locations of the HCPs from pharmacists, defendant WOROBOFF, defendant WILLARD, and their co-conspirators set up local mailing addresses for the Telemedicine Company to use on prescriptions in those states.
- m. Similarly, in order to further conceal the location of the HCPs and give the misimpression that the prescriptions had been written by HCPs close to the patients, the Telemedicine Company established multiple phone numbers that were local to the pharmacies. For example, on or about May 8, 2015, defendant WILLARD sent an email to defendant WOROBOFF and others noting that a new phone number with a northern California area code "MUST go on all scripts" and asking defendant WOROBOFF whether they should "get a number that is a las vegas area code?" In another email dated March 31, 2015, an employee of the Telemedicine Company explained to defendant WILLARD that the "the local numbers in each state" would be funneled to a common phone number called the "TMI Pharmacy Line," which would be staffed by employees of

the Telemedicine Company. In other words, while the pharmacists would believe that they were calling an HCP at a local number, in reality, Telemedicine Company employees located in the Philippines would be responding to the inquiries.

- n. In order to generate increased Compound and DME Orders, the defendants failed to comply with state and federal telemedicine rules requiring video consultations. For example, on or about May 21, 2014, defendant WILLARD was advised in an email from a Marketer that "face to face" communications were "now required by Florida." On or about May 21, 2014, defendant WILLARD responded that "Video will be coming on-line in the next 60 days." Nonetheless, the Telemedicine Company did not begin to utilize video technology until at the earliest in or around 2017, even though it continued to issue Compound and DME Orders for beneficiaries in Florida.
- o. The fraudulent Compound Orders that defendant WOROBOFF, defendant WILLARD, defendant MILLS, and defendant THU caused the Telemedicine Company to generate, and the fraudulent DME orders that defendant WOROBOFF and defendant WILLARD caused the Telemedicine Company to generate, were subsequently billed to federal and private health care benefit programs. The fraudulent Compound and DME Orders generated by the Telemedicine Company resulted in losses to TRICARE and other federal and private health care benefit programs of at least approximately \$37 million.

All in violation of Title 18, United States Code, Section 1349.

COUNT TWO (Conspiracy to Violate the Federal Anti-Kickback Statute)

- 1. The allegations in Paragraphs 1 and 3 to 4 of Count 1 of this Indictment are realleged here.
- 2. From in or around May 2014 through in or around April 2017, in the District of New Jersey, and elsewhere, defendants

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did knowingly and intentionally conspire and agree with each other and others to commit an offense against the United States, that is to knowingly and willfully offer and pay remuneration, including any kickback, bribe, and rebate, directly and indirectly, overtly and covertly, in cash and in kind, to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, namely Medicare and TRICARE, contrary to Title 42, United States Code, Section 1320a-7b(b)(2)(A).

Goal of the Conspiracy

3. The goal of the conspiracy was for the defendants and others to unlawfully enrich themselves by exchanging bribes for Compound Orders.

Manner and Means of the Conspiracy

- 4. It was part of the conspiracy that:
- a. Beginning in or around May 2014, defendant WOROBOFF, defendant WILLARD, defendant MILLS, and their co-conspirators agreed to enter

into agreements with HCPs whereby the HCPs would provide Compound Orders in exchange for kickback payments, including defendant THU and Physician-1.

- b. From at least as early as in or around July 2014, defendant WOROBOFF, defendant WILLARD, and defendant MILLS agreed with defendant THU that the Telemedicine Company would pay her kickbacks of approximately \$35 for each compound prescription.
- c. Defendant THU thereafter generated Compound Orders for TRICARE beneficiaries and others without speaking to the beneficiaries and in exchange for kickback payments.
- d. From at least as early as September 2014, defendant WOROBOFF, defendant WILLARD, defendant MILLS, and their co-conspirators agreed with Physician-1 that the Telemedicine Company would pay Physician-1 a kickback payment of \$25 for each compound prescription.
- e. As a result of this scheme, TRICARE paid at least approximately \$110,000 in reimbursements for Compound Orders generated through the payment of kickbacks.

Overt Acts

- 5. In furtherance of the conspiracy, and in order to effect the goal thereof, the defendants and others committed or caused the commission of the following overt acts in the District of New Jersey and elsewhere:
- a. On or about October 17, 2014, Physician-1, located in New Jersey, received a kickback payment of approximately \$1,395 from the

Telemedicine Company, in exchange for which Physician-1 provided approximately 55 Compound Orders to the Telemedicine Company.

- b. On or about November 12, 2014, defendant THU received a kickback payment of approximately \$8,325 from the Telemedicine Company, in exchange for which defendant THU provided approximately 239 Compound Orders to the Telemedicine Company.
- c. On or about November 17, 2014, Physician-1, located in New Jersey, received a kickback payment of approximately \$2,300 from the Telemedicine Company, in exchange for which Physician-1 provided approximately 92 Compound Orders to the Telemedicine Company.
- d. On or about January 20, 2015, defendant THU received a kickback payment of approximately \$8,810 from the Telemedicine Company, in exchange for which defendant THU provided approximately 252 Compound Orders to the Telemedicine Company.
- e. On or about February 18, 2015, defendant WOROBOFF, defendant WILLARD, and another individual received an email from an employee of the Telemedicine Company. The email attached an excel spreadsheet calculating both the legitimate compensation earned by each HCP and, separately, the kickbacks earned by HCPs as a result of generating prescriptions. The calculation for defendant THU provided that defendant THU had earned kickbacks in the amount of approximately \$5,565 for approximately 159 "Consultations (Scripts)" issued to approximately 87 patients. The

spreadsheet noted that this portion of defendant THU's compensation was based on payments of "\$35 per script."

f. On or about February 18, 2015, defendant THU received a kickback payment of approximately \$5,565 from the Telemedicine Company in exchange for which defendant THU provided approximately 159 Compound Orders to the Telemedicine Company.

All in violation of Title 18, United States Code, Section 371.

FORFEITURE ALLEGATION AS TO ALL COUNTS

1. Upon conviction of one or more of the Federal health care offenses, as defined in 18 U.S.C. § 24, alleged in Counts 1 and 2 of this Indictment, the defendants charged in each respective count shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(7), all property, real or personal, obtained by the defendants charged in each respective count that constitutes or is derived, directly and indirectly, from gross proceeds traceable to the commission of the offenses charged in Counts 1 and 2 of this Indictment.

SUBSTITUTE ASSETS PROVISION (Applicable to All Forfeiture Allegations)

- 2. If any of the above-described forfeitable property, as a result of any act or omission of the defendants:
 - (a) cannot be located upon the exercise of due diligence;
 - (b) has been transferred or sold to, or deposited with-, a third person;
 - (c) has been placed beyond the jurisdiction of the Court;
 - (d) has been substantially diminished in value; or
 - (e) has been commingled with other property which cannot be subdivided without difficulty;

the United States shall be entitled to forfeiture of substitute property, pursuant to 21 U.S.C. § 853(p), as incorporated by 18 U.S.C. § 982(b).

RACHAEL A. HONIG

Acting United States Attorney

CASE NUMBER: 21 -907-ES

United States District Court District of New Jersey

UNITED STATES OF AMERICA

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GEORGE WILLARD, JR., RANDALL MILLS, and DAVID WOROBOFF, LE THU

INDICTMENT FOR

18 U.S.C. §§ 371, 1349, and 2

A True Bill.

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